REMARKS

The present application contains Claims 1-206, the status of which is as follows:

(a) Claims 7 and 11-15 are as originally filed.

(b) Claims 6, 10, 55-56, 59-64, and 151-177 were previously amended.

(c) Claims 10, 59, 151, 158-159, 161, 164, 168-172, and 177 have been currently amended.

(d) Claims 205 and 206 were previously added, and have been currently amended.

(e) Claims 152-154, 156-160, 165, and 169-171 were withdrawn in response to a restriction requirement.

(f) Claims 1-5, 8, 9, 16-54, 57-58, 65-150, and 178-204 were previously canceled.

No new matter has been added. Reconsideration is respectfully requested.

Applicants thank Examiner Evanisko for the courtesy of a personal interview with Applicants' representative Sanford T. Colb (Reg. No. 26,856), held in the USPTO on March 9, 2006. At the interview, Mr. Colb argued the patentability of independent Claims 10, 59, 205 and 206 under 35 U.S.C. §112, first paragraph, and independent Claims 10 and 59 under 35 U.S.C. §102(e) and/or 103(a) over Mower, U.S. Patent No. 6,141,586 ("Mower"), as described hereinbelow. As also described hereinbelow, Mr. Colb proposed amendments to Claims 10, 59, 205, and 206 to overcome the rejections under 35 U.S.C. §§102(e) and 103(a) over Kroll et al., U.S. No. 5,978,703 ("Kroll"). Although no agreement was reached regarding these rejections, the Examiner agreed to consider Applicants' arguments when submitted in a written response.

Applicants thank the Examiner for allowing Claims 6, 7, 55, and 56 in the official action dated October 19, 2005.

Claims 10-15, 59-64, 151, 155, 161-164, 166-168, 172-177, 205, and 206 were rejected under 35 U.S.C. §112, first paragraph, for failure to comply with the written description requirement. The Examiner argued that the "overall duration greater than 8 ms" recited in independent Claims 10, 59, 205, and 206 does not include the "small, initial fraction of signal 60," and therefore is not supported by the specification.

Applicants respectfully submit that small, initial fraction 60 is included in the "overall duration greater than 8 ms," and that the amendments thus find support in the specification as filed. The Examiner's attention is drawn to Fig. 3A of the present application. As shown in the figure, the signal typically begins with "an initial cathodic pulse 62," and the signal has an overall duration T_2 (p. 16, lines 16-20). Initial cathodic pulse 62 initiates action potential propagation in order to pace the heart (p. 17, lines 16-17), while the remainder of the signal causes "improvement of one or more cardiac performance parameters" (p. 6, lines 8-9).

The "time of initiation of application of that portion of the signal that initiates action potential propagation [emphasis added]," as recited in Claims 10, 59, 205, and 206, is the start of initial cathodic pulse 62 in Fig. 3A, which coincides with the start of period T_2. The small, initial fraction 60 occurs at the beginning of initial cathodic pulse 62, and is thus included in the overall duration of period T_2 that is greater than 8 ms. Applicants thus submit that Claims 10-15, 59-64, 151, 155, 161-164, 166-168, 172-177, 205, and 206 are patentable under 35 U.S.C. §112, first paragraph.

Claims 10-13, 59-62, 151, 155, 161, 164, 166, 168, 172-173, and 175-177 were rejected under 35 U.S.C. §102(e) over Kroll. The Examiner argued that Kroll describes the application of a series of 10 pulses each having a duration of 1-5 ms, for a total duration of 10-50 ms, which is greater than 8 ms. Applicants have amended Claims 10 and 59 to more explicitly recite that the pacing signal has "an overall duration within a single heartbeat greater than 8 ms." In contrast, Kroll describes applying each 1-5 ms pulse within a separate heartbeat:

> A series of forcing pulses 60 are shown in FIG. 4. The pulses are approximately 50 V in amplitude with a spacing of approximately 500 ms. . . . An interval of 500 ms corresponds to a heart rate of 120 beats per minute" (col. 4, lines 42-49).

Applicants thus submit that Claims 10-13, 59-62, 151, 155, 161, 164, 166, 168, 172-173, and 175-177 are patentable under 35 U.S.C. §102(e) over Kroll.

This amendment is broadly supported by context throughout the specification as filed. The pacing signal described in the specification and claimed in Claims 10 and 59 is characterized as an "extended pacing signal." The Background of the Invention describes conventional pacing signals in some detail, including figures. It was well known in the art at the time of filing of the present application that conventional pacing signals are applied within a single cardiac cycle (i.e., a pacing signal is applied, and this initiates a heartbeat). It is clear from the entire specification, taken in context, that the novel extended pacing signals described in the specification share this fundamental characteristic with conventional short pacing signals. In addition, the specification describes initiating the application of each signal using a trigger generator:

> Generator 50 comprises a waveform generator 56 and, preferably, a DC offset generator 54, which are synchronized by a trigger generator 52. . . . Trigger generator 52, waveform generator 56, DC offset generator 54 and output stage 58 comprise electrical elements that are known in the

> pacemaking art, but are suitably modified to provide relatively longer pulses and higher energy levels (p. 16, lines 8-14).

It was well known in the art at the time of filing the present application to use a trigger signal to synchronize the application of pacing pulses with the patient's cardiac cycle.

Furthermore, the specification states:

> T_2 [the overall duration of the signal] is preferably kept less than about 100 ms in order to reduce or eliminate the likelihood that a later portion of signal 60 will give rise to an additional, arrhythmic stimulation of the heart tissue (p. 17, lines 17-19).

If the signal has an overall duration of 100 ms, the signal clearly falls within a single heartbeat.

Claims 10, 12-15, 59, 61-64, 151, 155, 161, 162, 164, 166, 168, 172, 173, and 177 were rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Mower. The Examiner argued that Mower describes the application of a pacing signal having a duration of greater than 8 ms "from a time of initiation of application of the signal that initiates action potential" (p. 5 of the office action).

The Examiner's attention is drawn to Fig. 5 of Mower, and the description thereof in the specification. Mower describes a pacing signal that has two phases:

- "a first stimulation phase, comprising low level, long duration anodal stimulation 502 having amplitude 504 and duration 506"; and
- "This first stimulation phase is immediately followed by a second stimulation phase comprising cathodal stimulation 508 of conventional intensity and duration" (col. 8, lines 35-41, emphasis added).

Applicants respectfully submit that the Examiner has not correctly characterized Claims 10 and 59 by omitting the key phrase "that portion of the signal." The pacing signal recited in Claims 10 and 59, as amended, has a duration greater than 8 ms "from a time of initiation of application of that portion of the signal that initiates action potential propagation," i.e., from the start of initial cathodic pulse 62, as shown in Fig. 3A of the present application. The part of Mower's signal applied after initiation of that portion of Mower's signal that initiates action potential propagation (i.e., the "second stimulation phase") has a duration of only 0.3 to 1.5 ms (col. 8, line 50). The extended, anodal, "first stimulation phase" of Mower's signal is applied before the short, cathodal, portion of Mower's signal that initiates action potential propagation.

The Examiner further argued that the first phase of Mower's signal is not necessarily subthreshold, i.e., of a strength insufficient to generate action potentials: "Although Mower says that the anodal portion [the first portion] could be subthreshold, this occurs in an 'alternative embodiment' (column 8, line 41)" (p. 5 of the office action). Applicants respectfully submit that the Examiner has not correctly characterized Mower. It is true that the subthreshold option occurs in an alternative embodiment. However, in both of the relevant alternative embodiments (numbers 1 and 2), Mower describes the first phase of the signal as being subthreshold:

> In differing alternative embodiments, anodal stimulation 502 is: 1) at maximum subthreshold amplitude; 2) less than three volts; 3) of a duration of approximately two to eight milliseconds; and/or 4) administered over 200 milliseconds post heart beat. Maximum subthreshold amplitude is understood to mean the maximum stimulation amplitude that can be administered without eliciting a contraction (col. 8, lines 41-48).

Several lines later, Mower again makes it clear that the first phase of stimulation is subthreshold: "In the manner disclosed by these embodiments, as well as those alterations and modifications which can become obvious upon the reading of this specification, a maximum membrane potential without activation is achieved in the first phase of stimulation" (col. 8, lines 55-59 [emphasis added]). Mower does not describe an embodiment in which activation is achieved during the first phase of stimulation.

Applicants thus submit that Claims 10, 12-15, 59, 61-64, 151, 155, 161, 162, 164, 166, 168, 172, 173, and 177 are neither anticipated by nor obvious over Mower.

Although the Examiner did not explicitly state so, Claims 205 and 206 were rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over, Mower. Claims 205 and 206 recite that the extended pacing signal comprises "a single extended pulse." Regarding the rejection under 35 U.S.C. §102(e), Applicants submit that Claims 205 and 206 are not anticipated by Mower for the same reasons given above for Claims 10 and 59.

With regard to the rejection under 35 U.S.C. §103(a), the Examiner argued that even if Mower does not disclose Applicants' pacing signal having a single extended pulse:

> It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the biphasic cardiac pacing signal as taught by Mower with the pacing signal being greater than 8 ms from a time of initiation of application of the signal that initiates action potential propagation and that the pulse is a single pulse. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the biphasic cardiac pacing signal as taught by Mower with the pacing signal being greater than 8 ms from a time of initiation of application of the signal that initiates action potential propagation and the pulse being a single pulse, because Applicant has not

> disclosed that the pacing signal being greater than 8 ms from a time of initiation of application of the signal that initiates action potential propagation or the pulse being a single pulse provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the biphasic pulse being greater than 8 ms from the beginning of the pulse as taught by Mower, because the pulse does not leave a net charge on the electrodes and improves contraction while damage to the tissue adjacent to the electrodes is diminished (pp. 5-6).

As described hereinabove with respect to Claims 10 and 59, Applicants respectfully submit that the Examiner has not correctly characterized Claims 205 and 206 by omitting the key phrase "that portion of the signal" that initiates action potential propagation. The part of Mower's signal applied after initiation of that portion of Mower's signal that initiates action potential propagation (i.e., the "second stimulation phase") has a duration of only 0.3 to 1.5 ms (col. 8, line 50). The Examiner's argument that it would have been obvious to substitute a single pulse for Mower's train of biphasic pulses is thus moot.

Dependent Claims 163 and 167 were rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over, Mower. In light of the suggested patentability of Claim 59, from which these claims indirectly depend, the Applicant submits that Claims 163 and 167, being of narrower scope, are allowable.

Dependent Claim 174 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kroll or Mower. In light of the suggested patentability of Claim 59, from which this claim indirectly depends, Applicants submit that Claim 174, being of narrower scope, is allowable.

Claims 205 and 206 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kroll. As discussed hereinabove with respect to Claims 10 and 59, Applicants have amended Claims 205 and 206 to more explicitly recite that the pacing signal has "an overall duration within a single heartbeat greater than 8 ms." In contrast, Kroll describes applying each 1-5 ms pulse within a separate heartbeat (col. 4, lines 42-49). The Examiner's argument that it would have been obvious to substitute a single pulse for Kroll's train of pulses is thus moot.

Applicants have currently amended Claims 151, 158, 159, 161, 164, 168-172, and 177 to correct an error in claim dependency that was inadvertently introduced in the previous amendment.

Applicants have currently amended the last element of Claims 10, 59, 205, and 206 to recite that the signal amplitude is "sufficient neither for cardioversion nor for defibrillation." This amendment is not being made in response to any rejection made by the Examiner or suggested by the Examiner during the interview of March 9, 2006, nor to differentiate these claims over any other art of which Applicants are aware. This amendment finds verbatim support in the specification: "Preferably, the electrical current applied in each pulse is substantially greater than twice the threshold required for pacing, and more preferably, greater than three times the threshold, although still substantially less than a level that would be required for cardioversion or defibrillation" (p. 5, lines 25-28 [emphasis added]).

Claims 152-154, 156-160, 165, and 169-171 were withdrawn in response to a restriction requirement. Given the suggested patentability of independent Claims 10 and 59, from which these non-elected claims directly or indirectly depend, Applicants respectfully submit that the restriction requirement with respect to these withdrawn claims should be withdrawn (MPEP 821.04).

Applicants believe the amendments and remarks presented hereinabove to be fully responsive to all of the grounds of rejection raised by the Examiner. In view of these amendments and remarks, Applicants respectfully submit that all of the claims in the present application are now in order for allowance. Notice to this effect is respectfully requested.

Respectfully submitted,

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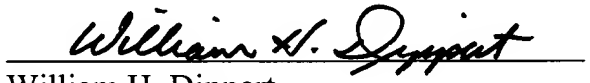

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